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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,492	05/23/2005	Andreas Menne		1537

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EXAMINER	
ABRAHAM, SALIEU M	
ART UNIT	**PAPER NUMBER**
3768	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,492	MENNE ET AL.	
	Examiner	Art Unit	
	Salieu M. Abraham	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5545124 to Krause (Krause) in view of US Pat. No. 5160336 to Favre (Favre)

In Reference to Claim 1

Krause teaches:

A medical instrument for the treatment of biological tissue, comprising:

a) a means for generating extracorporeal pressure waves, (see figure 1, reference mark 1)

and

b) a transmission element (2) for coupling the pressure waves into the body of living beings, (see figure 1, reference mark 2 and figure 2, reference mark 7)

d) the transmission element (2) has an inwardly curved exit boundary surface configured such that the pressure waves may be coupled into the biological tissue and may be focused in the biological tissue (see figure 2, reference mark 7)

However, Krause fails to teach pressure wave coupling to the "transmission element by an impact member (10) hitting a transmission element (2) and the pressure wave propagates in the transmission element (2)".

In the same field of endeavor, Favre teaches the use of a projectile or ballistic-type shock wave generator for medical purposes that is "of simple and inexpensive construction" (see column 2, lines 5-10 and lines 29-47).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have substituted the "ballistic-type" shock wave generator of Favre in the medical instrument of Krause in order to have a more simple and cost-effective instrument for medical treatments using shock waves as explicitly taught by Favre.

In Reference to Claim 2

Krause in view of Favre has been shown to teach all of the limitations of claim 1. Favre further discloses:

The medical instrument as described in claim 1, characterized in that wherein the means for generating the pressure

waves is an impact member (10) guided in a housing and adapted to reciprocated by means of a drive means,

the impact member (10) exerting one or more impulses on the transmission element (2) and inducing a pressure wave

in the transmission element (2) due to the impulse, said pressure wave propagating to the exit boundary surface (19) of the transmission element (2). **(see abstract and column 2, lines 29-47).**

Therefore Krause in view of Favre meets all claim 2 limitations.

In Reference to Claim 3

Krause in view of Favre has been shown to teach all of the limitations of claim 2. Favre further discloses:

The medical instrument as defined in claim 2, characterized wherein the impact member (10) is arranged coaxially to the transmission element (2) (see figure 1, reference marks 6 and 12).

Therefore Krause in view of Favre meets all claim 3 limitations.

In Reference to Claim 4

Krause in view of Favre has been shown to teach all of the limitations of claim 1. Favre further discloses:

The medical instrument defined in claim 1, wherein the pressure wave source may be driven periodically, the impact member (10) and the transmission

element (2) being self-returnable. (see figure 1, reference marks 6, 10 and 12) and column 2, lines 35-54).

Therefore Krause in view of Favre meets all claim 4 limitations.

In Reference to Claim 5

Krause in view of Favre has been shown to teach all of the limitations of claim 1. Favre further discloses:

The medical instrument as defined in claim 1, wherein the impact frequency of the impact member (10) is about 1 to 30 Hz, preferably 1 to 12 Hz. (see column 2, lines 54-55).

Therefore Krause in view of Favre meets all claim 5 limitations.

In Reference to Claim 6

Krause in view of Favre has been shown to teach all of the limitations of claim 1. Favre further discloses:

The medical instrument as defined in claim 1, wherein a spring/damping element (15) is provided between the transmission element (2) and the housing (4). (see figure 1, reference marks 10, 6 and 9, and 12).

Therefore Krause in view of Favre meets all claim 6 limitations.

In Reference to Claim 7

Krause in view of Favre has been shown to teach all of the limitations of claim 1. Favre further discloses:

The medical instrument as defined in claim 1, wherein the exit boundary surface (19) of the transmission element (2) travels a stroke of less than 0.5 mm due to the impulse. (see column 3, lines 10-47)

Therefore Krause in view of Favre meets all claim 7 limitations.

3. Claims 8 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5545124 to Krause (Krause) in view of US Pat. No. 5160336 to Favre (Favre) further in view of US Pat. No. 4972826 to Koehler (Koehler).

In Reference to Claim 8

Krause in view of Favre has been shown to teach all of the limitations of claim 1. However, Krause in view of Favre fails to disclose:

The medical instrument as defined in claim 1, wherein an intermediate element (9) is arranged between the impact member (10) and the transmission element (2), which intermediate element passes the impulse from the impact member (10) to the transmission element (2).

Koehler, in the same field of endeavor, discloses a shock wave generator having a combination of intermediate and transmission elements for medical use (see abstract and figures 4, reference marks 19 and 18 and 5, reference marks 21-23,24-26 and 18). Koehler cites the power of this approach in being able to flexibly generate a plurality of

composite and more highly customized shock wave profiles for application to target area being treated (see abstract and column 1, lines 47-65 and column 2 lines 12-67).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have included the intermediate element of Koehler in the device of Krause in view of Favre in order to customize the resulting shock wave/pressure pulse impulses to be sent to the transmission element and subsequently to the targeted area of treatment as explicitly taught by Koehler.

In Reference to Claim 12

Krause in view of Favre has been shown to teach all of the limitations of claim 1. However, Krause in view of Favre fails to disclose:

The medical instrument as defined in claim 1, wherein the impedance-adjusting media (5) are provided between the exit boundary surface (19) of the transmission element (2) and the biological tissue for improving the coupling of the pressure wave into the biological tissue. (see column 3, lines 32-46). As discussed above for claim 8, Koehler asserts that the arrangement of the intermediate and transmission elements allows a more effective customization of the resulting pressure pulse for the targeted area (see column 3, lines 32-43).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have included the intermediate element of Koehler in the device of Krause in view of Favre in order to customize the resulting shock wave/pressure pulse impulses to be sent to the targeted area as explicitly taught by Koehler.

4. Claim 9 -11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US

Pat. No. 5545124 to Krause (Krause) in view of US Pat. No. 5160336 to Favre (Favre) further in view of US Pat. No. 4972826 to Koehler (Koehler) further in view of Examiner's Official Notice (EON).

In Reference to Claim 9

Krause in view of Favre has been shown to teach all of the limitations of claim 1. However, Krause in view of Favre fails to disclose:

The medical instrument as defined in claim 1, wherein the outer edges of the exit boundary surface of the transmission element are rounded or provided with a protective coating.

Koehler, in the same field of endeavor, discloses that the transmission and intermediate elements may take a variety of shapes, sizes and positions in order to customize the resulting pressure pulses as desired for a targeted area (see figures 4-9 and column 2, lines 57-67 and column 3, lines 47-66). Therefore, the shaping of the various elements used in configuring the pressure pulse is merely a matter of design choice and would be well within ordinary skill in the art.

In Reference to Claims 10 and 11

Krause in view of Favre has been shown to teach all of the limitations of claim 1. However, Krause in view of Favre fails to disclose:

(Re claim 10) The medical instrument as defined in claim 1, wherein the transmission element has a larger diameter at the exit boundary surface (19) than at the entry boundary surface (20), and

(Re claim 11) The medical instrument as defined in claim 1, wherein the transmission

element (2) is in the shape of an exponential horn.

As discussed claim 9, Koehler discloses that the intermediate and transmission elements may be arranged/ordered so as to make various shapes and further customize the pressure pulse profile produced. Koehler further discloses that the elements may be placed adjacent to one another, in effect producing a composite element, so as to produce a desired pressure pulse effect (see column 3, lines 58-67 and column 4, lines 1-5). It is well known in the art and case law to make multiple or a plurality of elements integral (e.g. a single unit) or shape the transmission element in order to produce a desired result with regard to the pressure pulse profile.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Balamuth, Pauli et al., Reichenberger, Rohwedder et al., and Weth et al. have been included because they all teach the use of acoustical devices and methods for generating pressure pulses or shock waves with therapeutic impact in vivo similar in scope to applicant's proposed invention.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Salieu M. Abraham whose telephone number is (571) 270-1990. The examiner can normally be reached on Monday through Thursday 9:30 am - 7:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

10/23/07 SA